



In the United States Patent and Trademark Office

Applicant: Joar Opheim
Serial Number: 09/416017
Filed: Oct. 6, 1999
Examiner: Isis Ghali
Group Art Unit: 1615

DECLARATION UNDER 37 C.F.R. Section 1.132

I, Joar Opheim declare and say as follows:

That I am a citizen of Norway and reside at 226 Kingsbury Drive, Aptos CA 95003.

That I am the inventor and applicant in the above identified patent application.

That I graduated from Bodo College in Bodo, Norway with a Intermediary degree in Mathematics in 1982, and that I graduated from M.I. University in Oslo Norway with an Intermediary degree in Science in 1984, and that I graduated from University of Oregon in Eugene, OR with a Bachelor degree in Science in 1986.

That I have applied my chemistry background over the last eleven (11) years to the study of fish oil processing improvements with the goals of improving quality (in particular freshness, purity, and concentration levels) and human consumption of Omega-3 fatty acids from fish. I founded Nordic Naturals in 1994, and am the managing partner. Nordic Naturals produces and sells fish oil based nutritional supplements which include Omega-3 fatty acids, including DHA and EHA and particularly fish oil products in flavored soft gelatin capsules.

That I am familiar with the above identified application and with the references sited by the examiner, namely Coapman (US 5,141,961), Brox (US 4,744,988), Stella (US 5,874,418), Story (US 5,738,871) and Garleb (US 5,444,054).

That I learned from experimentation in developing a palatable Omega-3 fatty acid fish oil supplement in a gelatin capsule that a palatable formulation requires both a pleasant tasting gelatin capsule, and a gelatin capsule composition which protects the fish oil from exposure to air. I also found that the addition of flavoring to the fish oil capsule filling improves the palatability further. I found that protecting the fish oil from contact with air is important for fish oil capsules because the fresh fish oil does not have the characteristic "fishy" odor and taste which results in the unpalatable character generally associated with fish oil. I found that once the "fishy" taste develops it can not be effectively covered up by flavoring and will be unpalatable to many people.

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That I tested a number of natural flavorings for the gelatin capsules and found that suitable flavoring occurred within a surprisingly narrow range of concentrations, between about 0.25% and 1.50% flavoring. I began by having a series of capsules made for me while varying the concentration and type of flavorings. I tested at least ten different natural flavors including strawberry, lemon, peppermint, peach, orange and plum. When these tests were started there was no guidance from the manufacturer of the capsules, because while they were a manufacturer of gelatin capsules, there had been no prior experience in making flavored soft gelatin capsules. I started using what turned out to be too high of concentrations of flavors between 5 and 10 % by weight of a flavor and found that these flavor concentrations were not palatable and indeed not consumable. After many tests I found that acceptable tasting gel capsules could be made between about 0.5 % and 1.5% from a wide range of natural flavorings. One of the final test panels for a series of capsules made with water soluble strawberry flavor (Firmenich 52311A) is given in Table 1, below (a copy of the original test memorandum dated 5/14/99 is attached hereto).

Table 1
Test Results for Flavored Gel Capsules (water soluble Firmenich Strawberry #52311, lot11050265 flavor)

Per Cent Flavoring (% of shell)	Observation
0.25%	Distorted Flavor
0.50%	Flat flavor-off flavor
0.75%	Good natural taste
1.00%	Somewhat distorted, harsh taste
1.25%	Harsh taste, after-taste
1.50%	Harsh taste - very soft capsule

Note that there was surprisingly an optimum taste between about 0.5% and 1.0% flavor, that below 0.5% was not a pleasant taste, and that as the flavor was increased above 1% to 1.5% the flavor became undesirable and the capsule also became unacceptably soft (see discussion of softness below).

That I found from long term testing that the most palatable flavoring for the capsule was different after a period of aging than for a fresh capsule depending on the nature of the oil used to fill the capsule (example EPA/DHA ratio and the total Omega -3 content) so that the most palatable flavor content of the gelatin capsules actually varied among 0.5%. 0.75% and 1% depending on the nature capsule filling.

That I also learned from making and storing capsules of oil over periods over eight months, that the hardness of the capsule was critical to making a capsule which would protect the fish oil from exposure to air (oxygen). Fresh fish oil takes on the characteristic "fishy" taste and odor when exposed to air. Once this characteristic is

present; even flavored capsules and oil are not palatable to many people. Allowing for the production, sales and distribution cycle, it is necessary for fish oil capsules to be stable for at least one to two years, so preventing this deterioration is critical to making a palatable fish oil supplement.

That I found that capsules having from about 6 to 10% water and from 0.25 to about 1.25% flavor had a particular hardness which does not allow the oil to deteriorate even over periods of time greater than eight months. The oil in softer capsules (the difference in hardness was readily noticeable by physical inspection), typically containing over 12% water content, took on an unacceptable odor in less than eight months. Harder capsules (less than about 3% water content) often developed small cracks which exposed the oil to air and developed an unacceptable odor. I also found that these harder capsules were also unpleasant to the taste because the flavor was not evenly distributed in the capsule.

For the above tests a typical capsule composition was 62% gelatin, 29% glycerol, 8% water and 1% natural flavoring. The water and flavoring content, of course, was varied keeping the ratio of other ingredients approximately constant.

That I also found the most palatable capsules when the filling and capsule contained about the same flavor concentration.

That I do not believe that it was known how to make a palatable fish oil supplement in a flavored gelatin capsule prior to my research and development, nor that the development would have been at all obvious to those skilled in the art.

That I directed Banner Pharmacaps Europe B.V. (Netherlands) in doing the research as described above, which led to the palatable fish oil capsules. Banner Pharmacaps is the second largest producer of soft gelatin capsules in the world and they were unable to lead me to a palatable formulation without the above described extended experimental program which lasted over eight months. They had no prior experience in producing a flavored gel cap palatable fish oil product.

In particular I do not believe that the prior art provides a basis to anticipate the following without having learned it by extensive experimentation:

1. That there would be an optimum flavor content, beyond which palatable fish oil capsules could not be made.
2. That the flavor content for a palatable capsule was between 0.25% and 1.25% for a wide variety of natural flavors.
3. That the flavor content would affect the capsule hardness.
4. That the water content of the capsules, would be a critical factor for producing a fish oil supplement capsule which retains palatability.
5. That the best range of water content for long term oil palatability is 6 to 10% water.

6. That water content above 12% or below 3% are inconsistent with long term palatability of fish oil capsules.

All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; these statements were made with the knowledge that willful false statements and the like so made are punishable by fine and imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issuing hereon.

Joar Oph
Joar Ophelheim

Date 10.8.00.

NORDIC NATURALS
The Ocean Product Authority

- Fax Cover Sheet -

Date: 05/14/99
Pages: 2

To: Hennie van Duynhoven
Banner Pharmacaps
Fax: 011-311-34624124
Phone: 011-311-34624100

From: Joar Opheim
Fax: 831-662-0382

Phone: 800-662-2544

Subject: ProDHA Flavor Concentration

Hi Hennie,

We have tested the various gelatin and oil concentration levels and have the following comments:

- 1) Please make sure that the excess softening issue caused by the flavor concentrate is resolved by increasing the sorbitol level.
- 2) See findings on next page.
For the ProDHA formula we clearly need to reduce flavor concentrate to 0.75% as amounts above this level create a harsh and distorted flavoring to both soft gel and oil. Amounts below 0.75% create a flat and unrecognizable taste not associated with strawberry whatsoever. Please let me know if there are any issues with adjusting both soft gel and oil concentration levels to 0.75%.

Regards,
Joar

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The Ocean Product Authority

- Fax Page 2 -

Shell (Firmenich #52311, lot #11050265)

		Comments
RDT	20-a	0.25 % flavor Distorted flavor
RDT	20-b	0.50 % flavor Flat flavor, off flavor
<input checked="" type="checkbox"/> RDT	20-c	<u>0.75 % flavor Good, natural taste</u>
RDT	20-d	1.00 % flavor Somewhat distorted, harsh taste

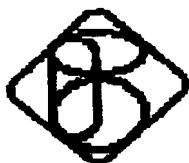
RDT 20-e 1.25 % flavor Harsh taste, after-taste

RDT 20-f 1.50 % flavor Harsh taste, very soft capsule, needs different polyol (sorbitol?)

FILL (EPAX 2050 TG #90223)

		Comments
RDT	21-a	0.25 % flavor Virtually unflavored
RDT	22-b	0.50 % flavor Flavored, still fishy taste
<input checked="" type="checkbox"/> RDT	23-c	<u>0.75 % flavor Stable flavor, minimal fishy taste</u>
RDT	24-d	1.00 % flavor Stable, yet harsh flavor
RDT	25-e	1.25 % flavor Distorted flavor, unpleasant
RDT	26-f	1.50 % flavor Unpleasant harsh flavor

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Banner Pharmacaps Europe BV

FAX

P.O. Box 5057, 5004 EA Tilburg, The Netherlands
Telephone: (31) 13 4624100 Telefax: (31) 13 4624124

Date: 12 May 1999

Ref.: FAX-HVD-99.098

To: Michele Ophain
Company: Nordic Naturals
Fax Number: 001631-6620382
CC: E.Baex, Sales
Pages: 8

From: Hennie van Duynhoven
Department: Formulation
Fax Number: (31) 13 4624124
E-mail: hvdvduynhoven@banpharm.nl

Subject: PRO DHA SOFTGEL PROJECT

Dear Michele,

Today we will send you lab trial formulations for fill and shell as listed on page 3 for the Pro DHA softgel with strawberry flavour (ref. NPT-2607; capsule size 7 oblong).

For the fill an oil soluble strawberry flavour is used; for the shell a water soluble flavour is used.

Product specifications for the used flavours are attached.
Further a CoA for the fish oil from Pronova is added.

The gel used for making the gelcapsules consists of gelatin, glycerol and water.

Please evaluate the trial formulations and let us know which flavour concentration you prefer for fill and shell.

To advice you on the strawberry flavour concentration for the shell following observations were made:

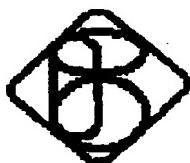
- with concentrations higher than 1% the gel gets cloudy
- with a concentration of 0.25% an off flavour is observed.

Our recommendation is to keep the flavour concentration for fill and shell as low as possible e.g. fill: 0.75% and shell 0.5%.

05/11/99 19:56

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Banner Pharmacaps Europe BV

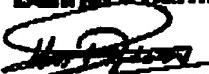
FAX

P.O. Box 5627, 5004 EA Tilburg, The Netherlands
Telephone: (31) 13 4624160 Telefax: (31) 13 4624124

To correct for the softening effect of the strawberry flavour we could modify the shell formula by adding a different polyol like sorbitol.
Question if this is allowed for this application?

If you have any further questions, please let me know.
Kind regards,

Banner Pharmacaps Europe BV


H.V. Duynhoven
Formulator

05/11/99 19:56 TX/RX NO. 0485 P.002

Received: 20/Aug/00 08:55 PM From: 8316620382 To: 9782468341 08/20/00 17:59 FAX 8316620382
Get faxes by email. Free. efax.com Page: 5 of 12
NORDIC NATURALS
Get faxes by email. Free. efax.com Page: 5 of 12

E-18

11 may 1999

Nordic, Fish oil capsules with strawberry flavour:

SHELL (GT-0000 + strawberry flavour (water soluble, Fippenich #52311A, lot# 11050265);

RDT-11may99-20a : 0.25% flavour N
 RDT-11may99-20b : 0.5% flavour M^o
 RDT-11may99-20c : 0.75% flavour G^o
 RDT-11may99-20d : 1.0% flavour
 RDT-11may99-20e : 1.25% flavour
 RDT-11may99-20f : 1.5% flavour

FILL (EPAX 2050 TG (Pronova, lot# 90223) + strawberry flavour (oil soluble, Fippenich #52311AH, lot# 11234454);

RDT-11may99-21a : 0.25% flavour
 RDT-11may99-21b : 0.5% flavour
 RDT-11may99-21c : 0.75% flavour
 RDT-11may99-21d : 1.0% flavour
 RDT-11may99-21e : 1.25% flavour
 RDT-11may99-21f : 1.5% flavour

05/11/99 19:56

SPB NO. 0485 TX/TX

P.003



EXHIBIT 2

E2-1

In the United States Patent and Trademark Office

Applicant: Joar Opheim

Serial Number: 09/416017

Filed: Oct. 6, 1999

Examiner: Isis Ghali

Group Art Unit: 1615

DECLARATION UNDER 37 C.F.R. Section 1.132

Supplementary Information to Exhibit 1 of Amendment B on experimental results
pertaining to flavored fish oil gelatin capsules

I, Joar Opheim declare and say as follows:

1. I am a citizen of Norway and reside at 117 Sea Terrace Way, Aptos CA 95003 and am the inventor and applicant. My background has been previously provided.
2. I have been experimenting with adding natural flavorings to the gelatin capsules and oil beginning in October 1997.
3. The initial experimenting concentrated on natural fruit flavors, orange, lemon, strawberry, peach and flavors thought to hide the flavor of the fish oil and which were popular with children, particularly mint and butterscotch.
4. The testing started with concentrations of 8-10% for each flavor and went down to 0.25% - 0.5%. We found for ALL of the flavorings that palatability increased with reduced concentration of flavoring in the shell between these limits. This result was a surprise to us and the lab which made the samples for us.
5. All of the test capsules were tested by a taste panel with a minimum of eight adults and from three to five children. The children's inputs were given considerable significance since the flavored products are widely taken by children.
6. The testing was conducted in two steps. The first step was to identify a palatable range of flavor concentrations and then to test in smaller steps within that range. In most cases, the second step was to test from 0.25% to 1.75% in 0.25% steps. The tests were done for oil and gel caps independently. Tests were also made to test for long term stability (8 months) in the 0.25% to 1.75% range in order to identify taste changes due to interactions with the oil.
7. Virtually all flavors tested have a palatability threshold between 0.25% and 1.75%. NO capsule was consumable when the flavor content of the shell was greater than 3%. I found this to be a surprising and unexpected result.
8. Palatability was maximized when the flavoring concentration in the oil was about 0.25% higher than the concentration in the shell.
9. When the oils had a low omega 3 concentration (<30%), generally more flavor was required (in both the oil and the shell) than when higher concentrations (>55%) were present in order to make a palatable fish oil capsule.

Joar Opheim

09/416017

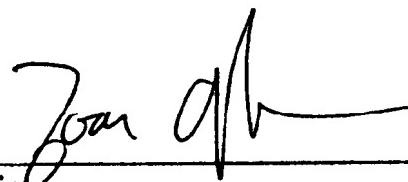
Page 1

10. When the oils had a high DHA concentration more flavoring is required to make a palatable capsule than when there is a high EPA concentration (0.25% to 0.50% more).
11. Low Omega 3 concentrations in oils consume the flavoring in the shell over time (eight months) and support a higher (up to 0.5% higher) initial concentration of flavoring.
12. Softening of the capsule shells due to addition of the flavoring is always an issue and is particularly exaggerated with citrus flavorings. Capsule softening often limits the amount of flavoring which can be added, usually to about 1.5%.
13. Softening of the shells can show up immediately if there is grossly too much flavoring, but can also show up after months of storage.
14. These experimental results and conclusions resulted from testing which was carried out under my supervision and was originally recorded in reports such as were included in my prior declaration (Exhibit 1 to Amendment B). I am currently unable to locate the reports other than those previously submitted.

All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; these statements were made with the knowledge that willful false statements and the like so made are punishable by fine and imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issuing hereon.

BY:

Joar Opheim



03.28.01

Date